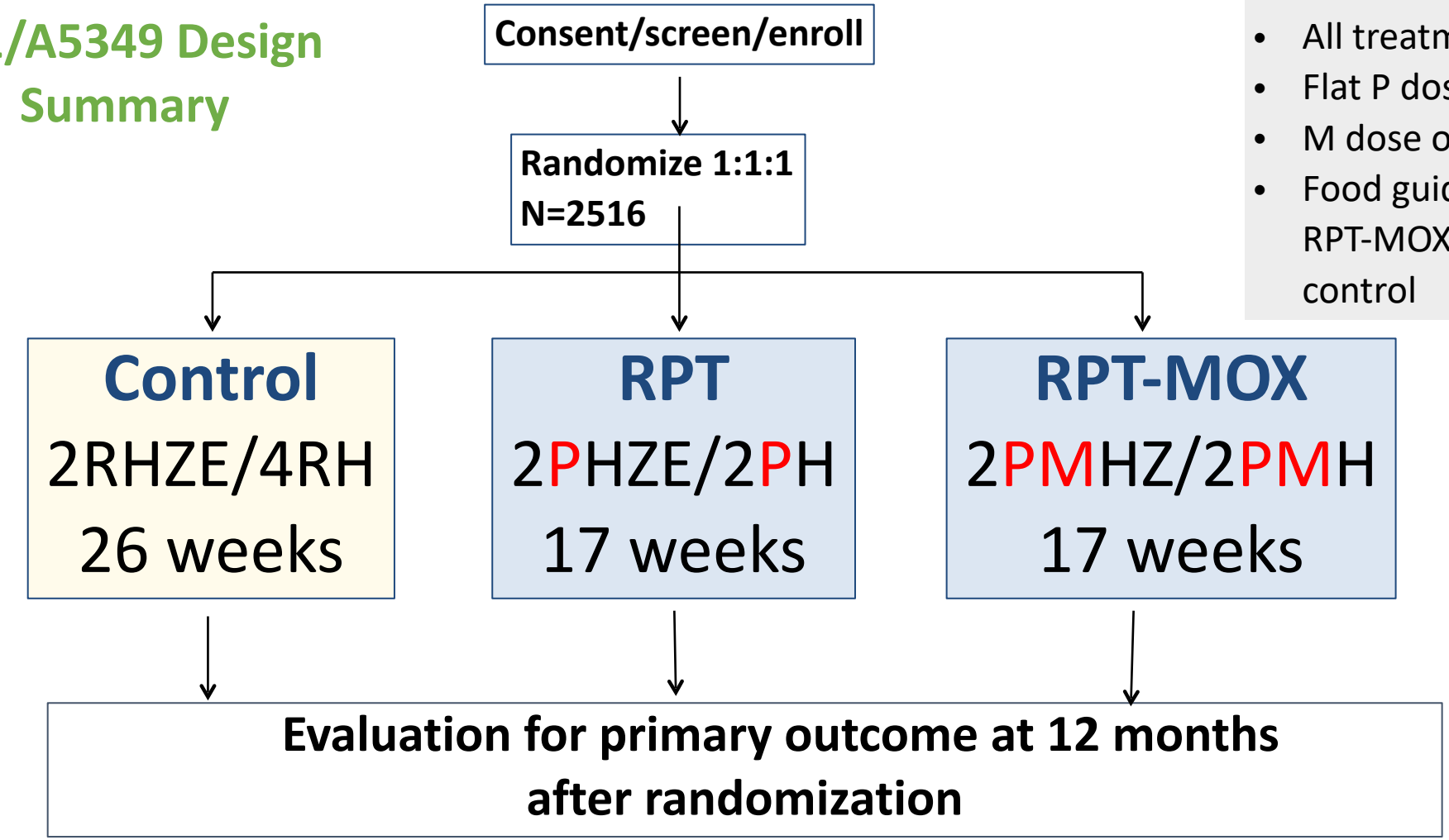
High-dose Rifapentine w/ or w/o Moxifloxacin for Shortening TB Treatment in Drug-susceptible TB TBTC Study 31/A5349

Dr Grace Muzanyi, Uganda-Case Western Reserve University Research Collaboration, Kampala, Uganda

2nd Annual PEPFAR Uganda Science Summit
Reaching and Maintaining Epidemic Control
1st February 2021
Kampala Uganda (virtual)

Objective: Is a new 17 wk regimen non-inferior to the standard 26 wk TB treatment regimen?
Design: International, multicenter, randomized non-inferiority trial in HIV-uninfected & infected adults & adolescents

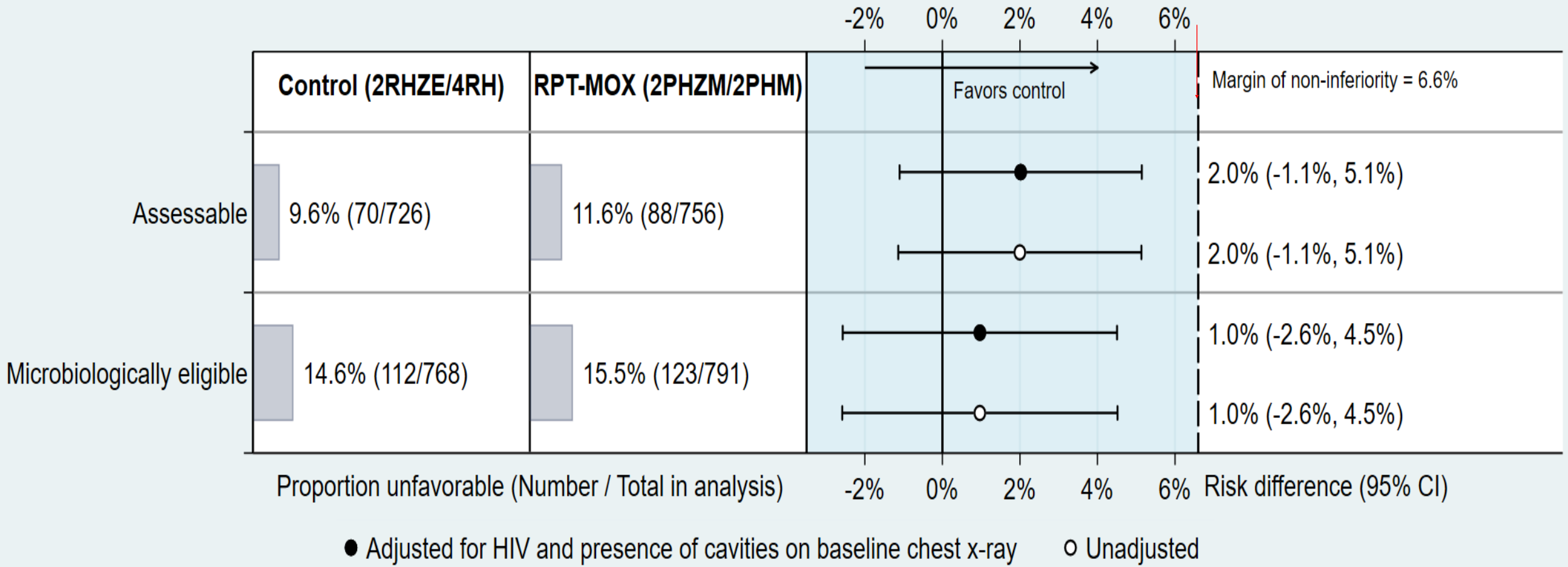
S31/A5349 Design Summary



Notes:

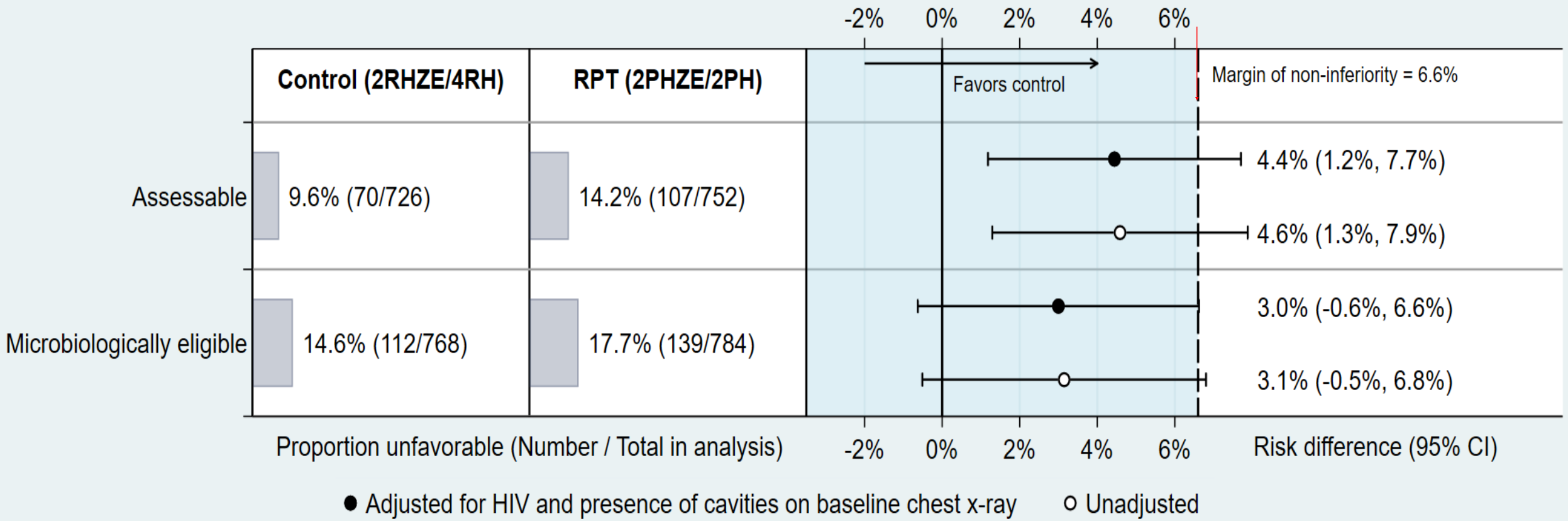
- All treatment: daily 7/7
- Flat P dose of 1200 mg
- M dose of 400 mg
- Food guidance: food with RPT, RPT-MOX, no food with control

S31/A5349 Primary Efficacy Results: RPT-MOX vs Control



RPT-MOX **meets non-inferiority** criteria for efficacy in all analyses

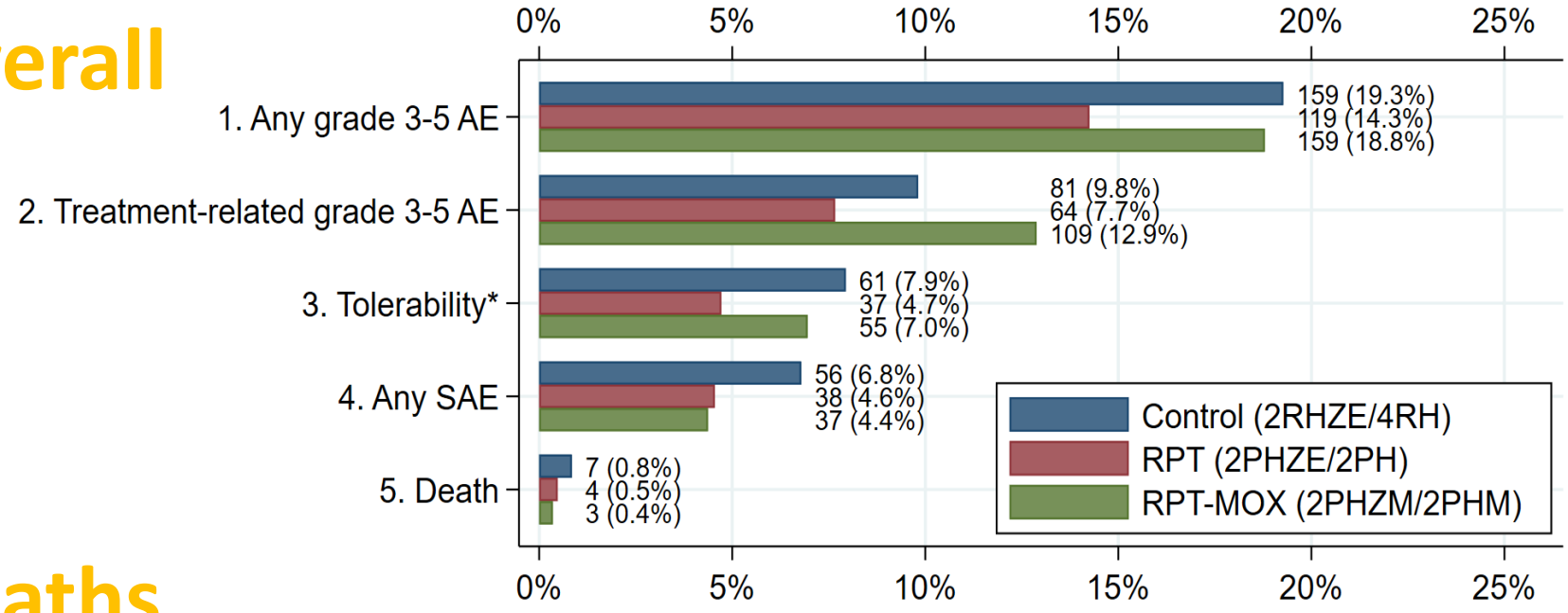
S31/A5349 Primary Efficacy Results: RPT vs Control



RPT **does not meet non-inferiority** criteria for efficacy in any analyses

Safety profile

Overall



Deaths

Description	Control (2HRZE/ 4HR) n (%) N=825	RPT (2HPZE/ 2HP) n (%) N=835	RPT-MOX (2HPZM/ 2HPM) n (%) N=846	Total n (%) N=2506
All deaths during treatment and follow-up	11 (1.3)	12 (1.4)	13 (1.5)	36 (1.4)
TB-related deaths	8 (1.0)	4 (0.5)	3 (0.4)	15 (0.6)

S31/A5349 Efficacy & Safety conclusions

- **4 mo RPT-MOX regimen (2HZPM/2HPM) met non-inferiority criteria for efficacy in all primary & secondary analysis populations & all sensitivity analyses**

- **4 mo RPT regimen (2HPZE/2HP) did not meet non-inferiority criteria for efficacy**

- **Both experimental regimens were safe and well tolerated**

- **Results were consistent & robust across sites & subgroups (adults, adolescents, HIV-infected individuals, etc)**

Implications for TB Control Efforts

- **Disseminate A31/ACTG5349 results in Uganda**
  - **Ministry of Health, National Tuberculosis Program (NTP), National Drug Authority (NDA), health care workers for agencies and associations.**
- **International community, Industry – Regimen accessibility globally.**
- **Once available internationally – fast track Uganda accessibility**
  - **Registration of rifapetine & moxifloxacin regimen for TB treatment in Uganda.**
  - **Discussions towards policy change towards this 4 month anti Tb treatment regimen**
  - **Ministry of Health, NTP, NDA, development partners – speedy efforts to make regimen available nationwide, once it's available for use**

Acknowledgments

- Study participants in Uganda
- Study staff in Uganda & the other 33 international sites that conducted this large trial.
- CDC Division of TB Elimination (sponsor)
- NIH/NIAID/DAIDS (sponsor)

OK to share slides with attendees and public after Summit?

- **Yes**